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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,083	08/30/2000	Gerald Wynn Hallworth	REF/Hallworth/Div	2803

7590

01/14/2002

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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

8

DATE MAILED: 01/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/651,083

Applicant(s)

HALLWORTH, GERALD WYNN

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/702,700.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Receipt is acknowledged of the Amendment C, received November 5, 2001.

The rejection of claims 22,23,35, and 38 under 35 U.S.C. 112, second paragraph, has been withdrawn due to applicant's current amendment deleting the objected to language from the claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 3,860,618 to Hartley *et al.*. Hartley *et al.* teach that according to a specific feature of their invention, sodium cromoglycate, having an effective particle size of from 0.01 to 10 microns, is useful for mixing with lactose of particle size from 30 to 80 microns in order to produce a composition suitable for inhalation (c 3, l 56-65). Hartley *et al.* also teach that there is no distinction between a single particle of a given size and an agglomerate of the same size which is composed of finer individual particles. Therefore, Hartley *et al.* teach that the lactose particle can be an agglomerate of many smaller particles. This disclosure anticipates the limitations of applicant's claim 18.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley *et al.*, as discussed above, and in view of the following comments. Hartley *et al.* are discussed above as teachings a composition suitable for inhalation comprising sodium cromoglycate and lactose particles. Hartley *et al.* do not teach that the lactose particles are between 150 and 1500 microns. However, it is the position of the examiner that the specific size of the lactose particles is a limitation which would be routinely determined by one of ordinary skill in the art. Furthermore, the determination of a particular size of a lactose pellet, is within the skill of the ordinary worker as part of normal optimization. Additionally, the burden is shifted to applicant to show a finding of unexpected results using specific sizes of lactose particles. Currently, it appears that the teachings of Hartley *et al.* fulfill the same purpose as applicant's claimed invention. Therefore, there appears to be no unexpected result based on the particular size of the lactose particles.

Hartley *et al.* also do not teach each of the specific drugs claimed by applicant. However, Hartley *et al.* do teach that their compositions may contain any of a wide variety of medicaments suitable for administration of inhalation (c 2, l 13-15). It is the

position of the examiner that one of ordinary skill in the art would have been motivated to use any drug, which is known for use in inhalation therapy, in the composition disclosed by Hartley *et al.*, which is taught to be successful for inhalation use. The expected result would be a successful composition for inhalation therapy.

In conclusion, Hartley *et al.* teach the generic concept that larger lactose particles are successful as carriers for particles of medicaments in order to create inhalation compositions. One of ordinary skill in the art would have been motivated to use any well known inhalation medicament in the teachings of Hartley *et al.*, to create a successful inhalation composition. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep

January 8, 2002

THOMAS K. PAGE  
REGISTERED EXAMINER  
JAN 10 2002